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## II. BACKGROUND

Plaintiffs filed this private securities fraud class action on November 7, 2005. They allege that defendants conspired to defraud the investing public by twice offering shares of the company's common stock for sale while failing to disclose their knowledge that a pivotal "Phase III" drug trial (the "STELLAR 3" study), on the efficacy of an experimental, targeted lung cancer chemotherapy treatment, Xyotax, would be a failure. (Dkt. #65 at 3-5, 12-13 and 32). Plaintiffs comprise the class of all persons who purchased or otherwise acquired defendants' common stock during the period of November 14, 2003 to March 7, 2005.

Defendant Cell Therapeutics ("CTI") is a "development stage" pharmaceutical company that designs, develops, and markets anti-cancer treatments. It's Chief Executive Officer, Dr. James Bianco, and Chief Medical Officer, Dr. Jack Singer, are also named as defendants. (Dkt. #65 at 2 and 8).

CTI hoped that the STELLAR 3 study would show that Xyotax increased the life spans of lung cancer patients over the current standard-of-care treatment, Taxol. (Dkt. #73 at 3). Thus, the study was divided into two "arms" – patients treated with Xyotax, and patients treated with Taxol. Which drug each patient received was at least formally "blinded" to CTI.

The initial blinded results of the trial showed that patients were living longer than the study assumed. Beginning in June of 2004, CTI issued a number of statements saying that these increased life spans were "encouraging," as they might demonstrate that Xyotax was more effective than Taxol. (Dkt. #65 at 36-37). In addition, representations were made about the nationalities of the study enrollees, and in which countries STELLAR 3 was taking place. STELLAR 3 was to be "mostly a U.S. and Western European Study." (Dkt. #65 at 35 and 38)

Meanwhile, the STELLAR 3 and other Xyotax trials were costing CTI millions of dollars. (Dkt. #65 at 3). As a result, the company turned to the open market to finance its continuing

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operations during the trials. (Dkt. #65 at 3). In July of 2004, CTI announced a public stock offering. On December 20 of the same year, the company also sought additional revenue through a private placement of CTI stock. Between the two offerings, CTI raised more than \$67 million. (Dkt. #65 at 3). Plaintiffs purchased CTI stock during these sales.

Ultimately, the optimism that CTI expressed publicly about STELLAR 3 was misplaced. The unblinded data clearly showed that patients treated with Xyotax lived no longer than patients treated with Taxol. (Dkt. #65 at 33). Rather, patients in *both* arms of the study had lived beyond the assumed "baseline" life span in essentially equal measures, giving an incorrect impression of Xyotax's effectiveness. (Dkt. #65 at 33). Simply put, STELLAR 3's baseline assumptions had been overly pessimistic.<sup>1</sup>

On March 7, 2005, CTI announced that STELLAR 3 had been a failure. As a result, the stock price dropped 47%, from \$10 per share on March 4 to \$5.25 per share at the close of trading on March 7. (Dkt. #65 at 32).

On May 18, 2005, CTI presented STELLAR 3's complete, "unblinded," results to the market. According to the company's statement, the majority of the study's enrollees were in fact from Eastern Europe and Russia, at 13% and 50%, respectively, rather than from the U.S., Canada, and Western Europe. (Dkt. #65 at 32-33). Further, the Eastern European and Russian enrollees were on average 10 years younger than their counterparts in Western Europe and the U.S., although those whose data were included in the unblinded results were apparently sick enough to qualify for the study.<sup>2</sup> (Dkt.

<sup>&</sup>lt;sup>1</sup> The estimated life-span of the study's participants, as approved by the FDA, was four months. (Dkt. #73 at 18-19).

<sup>&</sup>lt;sup>2</sup> There is some confusion about this point. Apparently there were 23 patients who CTI discovered were not sick enough to participate "midway through the study because they were not sufficiently symptomatic." (Dkt. #65 at 33 and Dkt. #73 at 21-22.) The final unblinded results excluded those patients.

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#65 at 33). Apparently, the Eastern European and Russian enrollees' relative youth and health resulted in longer median survival times, which in turn contributed to the erroneous impression that Xyotax was making patients live longer than those treated with Taxol. (*See* Dkt. #65 at 34-35).

Based on their loss caused by the decline in CTI's stock price, plaintiffs filed this lawsuit asserting that defendants violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78j(b) (2000), and Securities and Exchange Commission Rule 10b-5, 17 C.F.R. § 240.10b-5 (2005). They allege that during the class period, defendants carried out a plan which was intended to, and did, deceive the investing public and cause the members of the class to purchase CTI common stock at artificially inflated prices. (Dkt. #65 at 48).

Plaintiffs also allege that Dr. Bianco and Dr. Singer acted as controlling persons within the meaning of Section 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. § 78t(a) (2000), and so are each individually liable for CTI's alleged violation of Section 10(b). (Dkt. #65 at 51-52).

#### III. LEGAL STANDARDS

Defendants move to dismiss plaintiffs' claims pursuant to Fed. R. Civ. P. 12(b)(6) on the basis that the allegations in the complaint are insufficient to meet the stringent pleading standard of the PSLRA. (Dkt. #73). Plaintiffs' primary claim for liability, according to the defendants' motion, is supported by insufficient facts in the complaint to give rise to the required strong inference of intentional or reckless misconduct.

#### A. 12(b)(6) Standard of Review

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must dismiss a complaint if a plaintiff can prove no set of facts in support of his claim which would entitle him to relief. *Van Buskirk v. Cable News Network, Inc.*, 284 F.3d 977, 980 (9th Cir. 2002); *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001); *Love v. United States*, 915 F.2d 1242, 1245 (9th Cir. 1989). In deciding a motion to dismiss, the Court accepts as true all material

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allegations in the complaint and construes them in the light most favorable to the plaintiff. *See Newman v. Sathyavaglswaran*, 287 F.3d 786, 788 (9th Cir. 2002); *Associated Gen. Contractors v. Metro. Water Dist.*, 159 F.3d 1178, 1181 (9th Cir. 1998). However, conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss. *Associated Gen. Contractors*, 159 F.3d at 1181.

When a complaint is dismissed for failure to state a claim, "leave to amend should be granted unless the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986). Leave to amend is properly denied "where the amendment would be futile." *DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992).

## B. The Securities Exchange Act of 1934

Plaintiffs first claim that individual defendants, as well as corporate defendant, were engaged in a scheme to defraud the investing public in violation of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5. Plaintiffs also claim that the individual defendants, Dr. Bianco and Dr. Singer, are personally liable as "control persons" under Section 20(a) of the Exchange Act, 15 U.S.C. § 15 U.S.C. § 78t(a). To prove their claims, plaintiffs must show that:

(1) defendants made a false statement or omission with regard to a material fact; (2) in connection with the purchase or sale of a security; (3) with scienter; (4) upon which plaintiffs reasonably relied; and (5) that proximately caused the alleged loss.

*Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 125 S.Ct. 1627, 1631 (2005). Defendants do not dispute that the second and fourth elements are present. (Dkt. #78 at 8).

## C. The Heightened Pleading Standard for Private Securities Fraud Claims

To survive a 12(b)(6) motion governed by the PSLRA and Fed. R. Civ. P. 9(b), plaintiffs "must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless

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or conscious misconduct." *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 974 (9th Cir. 1999). To show a strong inference of deliberate recklessness, the bare minimum for pleading under the PSLRA, plaintiffs "must state facts that come closer to demonstrating intent, as opposed to mere motive and opportunity." *Id*.

Under the PSLRA, complaints alleging securities fraud must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). *See also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1222 (S.D. Cal. 2001).³ It has been noted that this requirement is an extension of the "particularity" requirement for pleading under Fed. R. Civ. P. 9(b). *See DepoTech*, 149 F. Supp. 2d at 1222-23.

This amounts to a requirement that the complaint set forth a particularized (time, place, manner) account of the allegedly fraudulent claims, as well as an explanation of why the statements were false and misleading when made. *Id. See also In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1404 (9th Cir. 1996), *In re GlenFed Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc) (superseded by PSLRA). Under the more stringent pleading standard of the PSLRA, however, private securities fraud claimants must plead with sufficient particularity *both* that the statements were false and misleading, *and* that they were made with the necessary intent to deceive, in order for claims to survive a motion to dismiss. *See Ronconi v. Larkin*, 253 F.3d 423, 428-29 (9th Cir. 2001).

<sup>&</sup>lt;sup>3</sup> Plaintiffs first disparage *DepoTech* as being "inapposite" by inaccurately claiming that defendants cite it as an unpublished Ninth Circuit case. (Dkt. #78 at 10, n.9). In fact, defendants cite the District Court's decision. (Dkt. #73 at 26). Plaintiffs then attempt to distinguish *DepoTech* by asserting that they pleaded in "great detail" the defendants' access to the patient case report forms ("CRFs"), while the plaintiffs in *DepoTech* did not. For the reasons set forth below, the Court is not persuaded by this argument.

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The *Ronconi* court instructs that when "considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), [the Court] must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or [with] deliberate recklessness made false or misleading statements to investors." *Id.* (quoting *Silicon Graphics*, 183 F.3d at 979) (internal quotation marks omitted).<sup>4</sup> Notably, when examining whether plaintiffs' allegations are sufficient to survive a motion to dismiss under the PSLRA, the Court "must consider *all* reasonable inferences to be drawn form the allegations, including inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir., 2002).

#### IV. DISCUSSION

Plaintiffs allege that CTI misled the market in three ways: (1) CTI could not have believed that the STELLAR 3's interim results were "encouraging," because its officers could glean from its interim results that Xyotax was not responsible for patients' increased survival times, (2) the study was so flawed that defendants must have known that its interim results meant something other than that Xyotax was making patients live longer than Taxol, and (3) STELLAR 3 was never primarily a U.S. and Western European study as was represented. In order to analyze the sum of plaintiffs allegations it is necessary to examine each alleged basis for fraud in turn.

## A. Defendants' Statements of Encouragement About STELLAR 3

Defendants challenge plaintiffs' allegations that the expressions of encouragement regarding

<sup>&</sup>lt;sup>4</sup> Plaintiffs incorrectly assert that *Silicon Graphics* "did nothing to raise the pleading standard beyond the most stringent existing standard [and] merely recognized that the PSLRA rejected the Second Circuit's view that allegations of motive, *alone*, could support a finding of scienter." (Dkt. #78 at 7, n.6). In fact, the Ninth Circuit Court of Appeals expressly recognized Congress' intent that the PSLRA raise the pleading standard above even the requirement that motive *and* opportunity could create a "strong inference" of recklessness or intent. *See Silicon Graphics*, 183 F.3d at 977-78. According to the court, "although facts showing mere recklessness or a motive to commit fraud and an opportunity to do so may provide some reasonable inference of intent, they are not sufficient to establish a *strong* inference of deliberate recklessness." *Id.* at 974 (emphasis in original).

STELLAR 3's interim results were fraudulent under the Exchange Act by arguing that the statements were true when made because the defendants were actually encouraged by the fact that the cancer patients in the study were living longer than expected, that plaintiffs failed to plead scienter with sufficient particularity to meet the strict requirements of the PSLRA, and that statements of mere encouragement are immaterial and not actionable as a matter of law. The Court is persuaded by defendants.

Plaintiffs argue that the following four statements were sufficiently misleading to constitute fraud under the Exchange Act:

- On June 7, 2004, CTI issued a press release stating that there were "encouraging developments in the STELLAR 3 pivotal trial." (Dkt. #65 at 36).
- During a November 9, 2004 conference call with investors, Dr. Bianco stated, "if you look at enrollment versus death rate there is a nice flat plateau effect on the survival curve which is very unique for clinical trial [sic] and very suggest[ive] that you may have a differences [sic] in arms." (Dkt. #65 at 37).
- On December 16, 2004, a Company press release stated that "the increase in . . . the survival estimates are very encouraging." (Dkt. #65 at 37).
- A final press release on January 27, 2005 stating that "The median and one-year survival estimates in STELLAR 3 are very encouraging." (Dkt. #65 at 37).

According to plaintiffs, at some point prior to these statements, Dr. Bianco reviewed individual enrolled patients' CRFs. (Dkt. #65 at 25-26). These CRFs can contain information that may indicate to a knowledgeable observer which drug a patient received in a controlled study – specifically for STELLAR 3, the differing amounts of time required for treatment with each drug. (Dkt. #65 at 23-25). At the same time, CTI was conducting test site audits on its own initiative and with the assistance of an outside company hired for that purpose. (Dkt. #65 at 23 and 28-29). Through these mechanisms, CTI developed extensive knowledge about how and where the study was being conducted, and could have potentially recognized which patients were receiving which drugs.

Without additional factual support, however, plaintiffs' allegations fail to meet the PSLRA's

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pleading standard. First, plaintiffs' conclusory allegation that Dr. Bianco must have learned that

STELLAR 3 was "materially flawed" fails to reach the level of sufficient particularity to compel the
necessary strong inference that he actually knew the study would fail. (Dkt. #65 at 30). As CTI
points out, the complaint fails to allege when the CRFs were reviewed, how many were examined, or

5 in what context Bianco looked at them. (Dkt. #73 at 15).

Plaintiffs' use of anonymous witnesses also fails to add the required specificity. Such pleading on information and belief is precisely that which requires plaintiffs to "state with particularity all facts" on which their belief is based. *See Silicon Graphics*, 183 F.3d at 983. Plaintiffs' confidential witnesses make only generalized and speculative statements concerning Dr. Bianco's knowledge of the trial's prospects. For example, one confidential source, "W-3," asserted merely that "Bianco knew everything" about STELLAR 3. (Dkt. #65 at 30). Similarly, W-3 does not help plaintiffs sufficiently plead that Bianco knew that the study would fail when he states that Bianco had "people who reported to him," and who told him "every possible detail" about STELLAR 3. (Dkt. #65 at 30).

Plaintiffs' attempt to analogize similar cases is also unavailing. All the cases on which plaintiffs substantially rely are distinguishable; in each case, the defendants either grossly misrepresented some specific material fact, or failed to disclose some concrete indication that they could not expect FDA approval for their product. *See In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983 (S.D. Cal. 2005); *In re CV Therapeutics, Inc. Sec. Litig.*, No. C 03-03709 SI, 2004 U.S. Dist. LEXIS 17419 (N.D. Cal. Aug. 5, 2004); *In re Amylin Pharm., Inc. Sec. Litig.*, NO. 01cv1455 BTM(NLS), 2003 U.S. Dist. LEXIS 7667 (S.D. Cal. May 1, 2003). The only cases cited based on substantially the same facts were decided in plaintiffs' favor under a less rigorous pleading standard. *See, e.g., In re Viropharma, Inc. Sec. Litig.*, No. 02-1627, 2003 U.S. Dist. LEXIS 5623, at \*32 (E.D. Pa. Apr. 3, 2003); *In re Cell Pathways, Inc. Sec. Litig.*, No. 99-752, 2000 U.S. Dist. LEXIS 8584 (E.D. Pa. June 20, 2000), at \*19.

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Finally, the complaint's "Additional Scienter Allegations," are also insufficient. (Dkt. #65 at 40-42). They supply nothing more than a plausible motive for misrepresentations on the part of defendants – keeping CTI's stock price artificially high prior to the STELLAR 3 results being made public. Plaintiffs undermine their own argument, however, by noting an entirely legitimate explanation for timing of the public stock offering and the primary placement: "The cash-burn from the Xyotax trial was financially crippling the Company," which in turn was "forced to raise money on the open market during the Class Period in order to finance its continuing operations." (Dkt. #65 at 3).

Plaintiffs failed to "plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct" with respect to their statements of encouragement in the interim results, or that the increased survival times in those results might tend to show a difference between Xyotax and Taxol. See Silicon Graphics, 183 F.3d at 974. Accordingly, the complaint must be dismissed with respect to the June 7, 2004, November 9, 2004, December 16, 2004, and January 27, 2005 statements of CTI and the individual named defendants. Because the Court finds that dismissal is required for these reasons, it need not address defendants' argument that mere statements of encouragement are immaterial and not actionable as a matter of law.

#### B. The Alleged Flaws of STELLAR 3

Plaintiffs also proffer extensive claims that STELLAR 3 was "flawed," that defendants knew about its flaws, and that defendants knew, as a result, that increased interim survival reports must not be "encouraging." (Dkt. #65 at 17-18 and 36-38). Thus, according to plaintiffs, defendants knew that the increased survival of the STELLAR 3 patients was the result of the incorrect baseline assumptions of the study, and of the presence of "healthier" patients in the Eastern European test sites.

As discussed previously, however, plaintiffs fail to plead facts sufficient to give rise to a strong inference that defendants were not, in fact, encouraged, or that they actually knew the study would

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ORDER **PAGE - 10**  fail. Plaintiffs also implicitly acknowledge that STELLAR 3's four-year baseline assumption was based on the best available science, and was approved by the FDA. (Compare Dkt. #65 at 17-18 with Dkt. #73 at 18). This alone would be sufficient to undermine any accusations related to flaws in that component of the study. Accordingly, because CTI's statements of encouragement fail to give rise to the necessary strong inference that CTI had the necessary intent to deceive stockholders, allegations that STELLAR 3 was "flawed" also provide no support for plaintiffs' arguments.

### C. The Demographics of STELLAR 3

Plaintiffs next allege that two statements in particular materially misled investors about the presence of Eastern European and Russian patients in the study:

- On November 14, 2003, Dr. Bianco stated during a presentation at the Credit Suisse First Boston Healthcare Conference about STELLAR 3 that "this is mostly a U.S. and Western European study."<sup>5</sup> (Dkt. #65 at 35).
- In response to a question by an analyst on February 28, 2005, regarding the potential for study contamination with patients who were not sick enough to qualify as PS2, and thus ineligible to participate, Dr. Bianco replied that "these patients sound like they are acute PS2s meaning that they are acutely sick with their lung cancer and that's probably more likely the case outside the U.S. than inside the U.S." (Dkt. #65 at 38).

Taking the allegations as true, and construing them in the light most favorable to the plaintiff, plaintiffs adequately allege that these statements were untruthful. First, plaintiffs adequately allege that Dr. Bianco could have known about the study's geographic composition by November 14, 2003. (See Dkt. #65 at 35-36). Plaintiffs also provide facts sufficient to support the inference that by

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<sup>&</sup>lt;sup>5</sup> Plaintiffs also allege that several other statements by the company or its officers "throughout the class period" gave the false impression that STELLAR 3 would be predominately a U.S. and Western European study. For example, during an October 24, 2002 conference call, Bianco stated that "a majority of [the] patients [enrolled would] originat[e] here in the United States," and during an April 24, 2002 conference call, that investors "should take some comfort in the fact that these important studies are being conducted in the U.S. and [Western] Europe." (Dkt. #65 at 22). Putting aside that these statements were not, in fact, made during the class period, the Court notes that the emphasized bracketed insertion in the second statement is a mischaracterization of the statement. Dr. Bianco actually said "U.S. and Europe" – without the "Western." (See Dkt. #73 at 24, n.26).

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February 28, 2005, Dr. Bianco at least knew that the patients in the United States test sites were not *less* sick that those in Eastern Europe. (*See* Dkt. #65 at 39-40).

Nonetheless, there is no reason to accept plaintiffs' inference that by misstating the geographic composition of STELLAR 3, defendants were intentionally or recklessly disregarding material facts. "To accept . . . that the court is required to consider only inferences favorable to [plaintiffs'] position would be to eviscerate the PSLRA's strong inference requirement by allowing plaintiffs to plead in a vacuum." *Gompper*, 298 F.3d at 896. Ultimately, plaintiffs' goal in referring these misstatements is once more to demonstrate that defendants could not have been encouraged by STELLAR 3's interim results, because they must have known that increased survival rates were due to "healthier" terminal cancer patients in Eastern Europe. Again, this does not amount to a particularized allegation that defendants were not indeed encouraged by the results, or that they intended to cover up the truth about STELLAR 3's outcome.

In sum, the Court concludes that the complaint must be dismissed for failure to state a claim with respect to CTI's statements on November 14, 2003, and February 28, 2005. Because plaintiffs fail to properly plead scienter with respect to any of the challenged statements, the Court need not address the element of loss causation.

## D. Control Person Liability, Safe Harbor, and Leave to Amend

Because Section 20(a) "control person" liability for Bianco and Singer is dependent on the liability of CTI under Section 10(b) of the Exchange Act, plaintiffs' Section 20(a) claim must also be dismissed. *See* 15 U.S.C. § 78t(a). Similarly, because the complaint fails to properly plead private securities fraud, it is unnecessary to review the question of whether or not CTI's statements were "forward looking," and whether the PSLRA's "safe harbor" provision for such statements applies under 15 U.S.C. § 78u-5(i)(1)(A) (2000).

Nonetheless, leave to amend should be granted unless the Court "determines that the pleading

1	could not possibly be cured by the allegation of other facts." See Fed. R. Civ. P. 15(a); Lopez v.
2	Smith, 203 F.3d 1122, 1127 (9th Cir. 2000). Here, plaintiffs could conceivably plead facts regarding
3	CTI's prior knowledge of STELLAR 3's failure. Accordingly, the Court must grant plaintiffs leave to
4	amend their complaint.
5	<u>v. conclusion</u>
6	The Court, having reviewed defendants' Motion to Dismiss (Dkt. #73), plaintiffs' Opposition
7	(Dkt. #78), and defendants' Reply (Dkt. #80), along with the remainder of the record, hereby finds
8	and ORDERS:
9	(1) Defendants' Motion to Dismiss the Consolidated and Amended Class Action Complaint
10	(Dkt. #73) is GRANTED and the Consolidated and Amended Class Action Complaint (Dkt. #65) is
11	DISMISSED.
12	(2) Plaintiffs' request for leave to amend is GRANTED. Plaintiffs shall file a Second
13	Consolidated and Amended Class Action Complaint no later than thirty (30) days from the date of this
14	Order.
15	(3) Defendants shall have thirty (30) days to file their Amended Answer, or otherwise respond
16	to such Complaint.
17	(4) The Clerk SHALL send a copy of this Order to all counsel of record.
18	DATED this 4th day of May, 2006.
19	De la companya della companya della companya de la companya della
20	RICARDO S. MARTINEZ UNITED STATES DISTRICT JUDGE
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